



OFFICE OF MANAGEMENT AND BUDGET

Executive Order 14081 Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. -- Request for Information; National Biotechnology and Biomanufacturing Initiative -- Measuring the Bioeconomy

AGENCY: Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President.

ACTION: Request for information.

SUMMARY: The Chief Statistician of the United States (CSOTUS) in the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, was charged in the Executive Order (E.O. 14081), “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy,” with improving and enhancing Federal statistical data collection designed to characterize and measure the economic value of the U.S. bioeconomy. The CSOTUS was also charged with establishing an Interagency Technical Working Group to recommend bioeconomy-related revisions for the North American Industry Classification System (NAICS) and the North American Product Classification System (NAPCS).¹ The bioeconomy refers to a segment of the total economy utilizing or derived from biological resources, and includes manufacturing processes, technologies, products and services. These may encompass, wholly or in part, industries and products including fuel, food, medicine, chemicals, and technology. This Federal Register Notice (FRN) is a Request for Information (RFI) seeking public input on existing or potential bioeconomy-related industries and products that are established, emerging, or currently embedded in existing industry/manufacturing processes.

DATES: To ensure consideration of comments on potential bioeconomy-related industries and products solicited in this notice, please submit all comments in writing as soon as possible, but no later than 45 days from the publication date of this RFI. Send comments on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Because of delays in the receipt of regular mail related to security screening, respondents are encouraged to send comments electronically (see **ADDRESSES** section, below).

ADDRESSES: Submit comments through *www.regulations.gov*, a Federal E-Government website that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Enter “OMB-2023-0012” (in quotes) in the Comment or Submission search box, click Go and follow the instructions for submitting comments.

Comments received by the date specified above will be included as part of the official record. Please include the Docket ID (OMB-2023-0012) and the phrase “National Biotechnology and Biomanufacturing Initiative -Measuring the Bioeconomy” at the beginning of your comments. Due to time constraints, electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Please indicate which questions in the **SUPPLEMENTARY INFORMATION** section you are responding to.

PRIVACY NOTICE: Information submitted in response to this RFI will be maintained in the OMB Public Input System of Records, OMB/INPUT/01 88 FR 20913. OMB generally makes comments received from members of the public available for public viewing on the Federal Rulemaking Portal at <https://www.regulations.gov>. As such, commenters should not include information that they do not wish to make publicly available, including information of a confidential nature, such as sensitive personal

information or proprietary information. Please note that if you submit your email address, it will be automatically captured and included as part of the comment that is placed in the public docket; however, www.regulations.gov does include the option of commenting anonymously. For more detail about how OMB may maintain and disclose submitted information, please review the System of Records Notice at 88 FR 20913.

Electronic Availability: **Federal Register** notices are available electronically at <http://www.regulations.gov>. The NAICS website at www.census.gov/naics contains NAICS United States **Federal Register** notices, Economic Classification Policy Committee (ECPC) Issues Papers, ECPC Reports, the structures, industry definitions, and related documents for all versions of NAICS United States.

Public Review Procedure: All comments and proposals received in response to this notice will be available for public inspection.

Instructions: Response to this RFI is voluntary. Respondents may provide input on any aspects of this solicitation. OMB is particularly interested in receiving comments on the questions posed by the Bioeconomy Interagency Technical Working Group (Working Group) tasked with developing recommendations for revisions to the NAICS, and/or the NAPCS. OMB's established process for updating existing Statistical Policy Directives includes technical evaluation of the current standard by an interagency working group composed of career Federal subject matter experts; additional technical research, testing, and analysis to close identified gaps; and solicitation and consideration of public comment on ways to improve the standard.

The final decisions regarding any changes to the standards are made by OMB. To provide useful information to the Working Group in their ongoing deliberations and ultimately to OMB in reviewing the Working Group's final recommendations, responders should acquaint themselves with current NAICS² and NAPCS³ structure and current

classifications. A brief description of the NAICS and NAPCS classification processes, structures and uses, as well as a description of this Interagency Technical Working Group (ITWG) are included in the **SUPPLEMENTARY INFORMATION** section.

An effective response should be concise, and if summarizing or depending on published works, please include citations and electronic links to reference materials, studies, research, and other empirical data that are not widely available. Questions posed below are those the Working Group deemed most significant and relevant to the its recommendations. and do not necessarily reflect or represent the positions of OMB or the agencies participating in the Working Group. The questions have been sorted into broad categories for ease of review.

Any information obtained from this RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development. OMB will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives.

FOR FURTHER INFORMATION CONTACT: For information about this request for comments, contact Anthony Nerino, Office of Management and Budget, 9215 New Executive Office Building, 725 17th St. NW, Washington, DC 20503, telephone (202) 395-1128.

SUPPLEMENTARY INFORMATION:

I. Background: The bioeconomy refers to a segment of the total economy utilizing and/or derived from biological resources, and includes manufacturing processes, technologies, products, and services. These may encompass, wholly or in part, industries and products including fuel, food, medicine, chemicals, and technology. Advances in biotechnology and biomanufacturing play a substantial role in addressing a range of

issues including health, climate change, energy, food security, agriculture, labor opportunities and economic growth.

E.O. 14081 directed Federal agencies to foster innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security. A critical component of this broad effort is an accurate measurement of the bioeconomy. Accurate data on bioeconomic manufacturing, industrial, and service activities may be used to assess growth across industrial sectors, inform Federal investments in research and development, guide private sector investments for scaling manufacturing efforts, assess emerging national and international economic opportunities, and foster the equitable distribution of health, food, and labor opportunities. Measuring U.S. industrial outputs and products provides critical information to a wide variety of private sector and Federal government stakeholders and requires accurate, reliable, independent measures that are also congruent with international measurements.

As part of its role as coordinator of the Federal statistical system under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(e)) (PRA), OMB, through the Chief Statistician of the United States (CSOTUS), must ensure the efficiency and effectiveness of the system as well as the integrity, objectivity, impartiality, utility, and confidentiality of information collected for statistical purposes.⁴ This statute also charges OMB with developing and overseeing the implementation of Government-wide principles, policies, standards, and guidelines concerning the development, presentation, and dissemination of statistical information.⁵ OMB maintains a set of statistical policy directives to implement these requirements and the NAICS is required by Statistical Policy Directive #8, North American Industrial Classification System: Classification of Establishments.⁶

II. NAICS and NAPCS: Recommendations to the Working Group on potential revisions to the NAICS and NAPCS requires some insight into what these classification systems are and how they are used. The NAICS is used to generate statistics on the U.S. and North American Economy. Additional information and updates for 2022 can be found in the **Federal Register Notice** (86 FR 35350, pp 35350-35365, Doc# 2021-14249).⁷

NAICS: NAICS is a system for classifying establishments (individual business locations) by type of economic activity. Its purposes are: (1) to facilitate the collection, tabulation, presentation, and analysis of data relating to establishments, and (2) to promote uniformity and comparability in the presentation and analysis of statistical data describing the North American economy. Federal statistical agencies use NAICS to collect and/or publish data by industry. It is also widely used by State agencies, trade associations, private businesses, and other organizations.

Mexico's Instituto Nacional de Estadística y Geografía (INEGI), Statistics Canada, and the United States Office of Management and Budget (OMB), through the ECPC, collaborated on NAICS to make the industry statistics produced by the three countries comparable. NAICS is the first industry classification system developed in accordance with a single principle of aggregation (i.e., producing units that use similar production processes should be grouped together in the classification). NAICS also reflects changes in technology and in the growth and diversification of services in recent decades. Industry statistics presented using NAICS are extensively comparable with statistics compiled according to the latest revision of the United Nation's International Standard Industrial Classification of All Economic Activities (ISIC, Revision 4).

For these three North American countries, NAICS provides a consistent framework for the collection, tabulation, presentation, and analysis of industry statistics used by government policy analysts, academics, researchers, the business community, and the public. Please note that NAICS is designed and maintained solely for statistical

purposes to improve and keep current this Federal statistical standard. Consequently, although the classification may also be used for various nonstatistical purposes (e.g., for administrative, regulatory, or taxation functions), the requirements of government agencies or private users that choose to use NAICS for nonstatistical purposes play no role in its development or revision.

Four principles that guide NAICS development are:

(1) NAICS is erected on a production-oriented conceptual framework. This means that producing units that use the same or similar production processes are grouped together in NAICS.

(2) NAICS gives special attention to developing production-oriented classifications for: (a) new and emerging industries, (b) service industries in general, and (c) industries engaged in the production of advanced technologies.

(3) Time series continuity is maintained to the extent possible.

(4) The system strives for compatibility with the two-digit level of the International Standard Industrial Classification of All Economic Activities (ISIC, Revision 4) of the United Nations.

NAICS uses a hierarchical structure to classify establishments from the broadest level to the most detailed level using the following format:

Sector	2-digit	Sectors represent the highest level of aggregation. There are 20 sectors in NAICS.
Subsector	3-digit	Subsectors represent the next, more detailed level of aggregation. There are 96 subsectors in NAICS 2022.
Industry Group	4-digit	Industry groups are more detailed than subsectors. There are 308 industry groups in NAICS 2022.
NAICS Industry	5-digit	NAICS industries, in most cases, represent the lowest level of three-country comparability. There are 698 five-digit industries in NAICS 2022.
National Industry	6-digit	

Sector	2-digit	<p>Sectors represent the highest level of aggregation. There are 20 sectors in NAICS.</p> <p>National industries are the most detailed level and represent the national level detail. There are 1,012 national industries in NAICS United States 2022.</p>
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To ensure the accuracy, timeliness, and relevance of the classification, NAICS is reviewed every five years to determine what, if any, changes are required.

NAICS 2022 is the fifth revision since OMB adopted NAICS in 1997. In response to public proposals during the NAICS 2022 revision process, the ECPC considered the feasibility, value, and impact of including new industries for the bioeconomy. In its final set of recommendations to OMB, the ECPC did not include bioeconomy revisions in NAICS 2022, but indicated that NAPCS 2022 could be used to identify new products of the bioeconomy, such as biobased chemical inputs, and to inform future revision cycles on significant emerging industries of the bioeconomy.

The ECPC cites concerns regarding the availability of data for emerging bioeconomy industries due in part to disclosure considerations. “However, the ECPC recognized that economic, statistical, and policy implications can arise when the industry classification system does not identify and account for important economic developments. The ECPC acknowledged that balancing the costs of change against the potential for more accurate and relevant economic statistics will require significant input from data producers, data providers, and data users.”⁸ OMB accepted the recommendations of the ECPC, and in its final decision, OMB noted the “importance of continued research and stakeholder engagement on [the bioeconomy] toward maintaining a relevant and objective statistical classification standard.”⁹

NAPCS: NAPCS is a comprehensive, market- or demand-based, hierarchical classification system for products (goods and services) that: (a) is not industry-of-origin based, but can be linked to the NAICS industry structure, (b) is consistent across the three

North American countries, and (c) promotes improvements in the identification and classification of service products across international classification systems, such as the Central Product Classification System of the United Nations.

NAPCS, a product classification system, and NAICS, an industry classification system, are independent but complementary. A product produced by multiple industries carries the same title, definition, and code in NAPCS, regardless of its industries of origin. Products can be linked to the industries that produce them, and industries can be linked to the products they produce.

The NAPCS structure comprises six hierarchical levels. At the highest level of the structure, there are 24 sections. Each section consists of subsections, divisions, groups, subgroups, and trilateral products.

NAPCS Level
Section Two digits
Subsection Three digits
Division Five digits
Group Seven digits
Subgroup Nine digits
Trilateral Product 11 digits

NAPCS provides a comprehensive list of products adopted by the U.S., Canada, and Mexico, and will be incrementally implemented into economic statistics programs. These detailed product data will provide policymakers and the business community with the information needed to understand our ever-changing economies. NAPCS provides

useful information to industry analysts to estimate market share for their firm or to investigate the growth of demand for the products of their firm with: (a) those for the industry as a whole, or (b) those that compete with or are closely associated with the products produced by the firm.¹⁰

III. ECPC: The ECPC is a standing committee responsible for the maintenance of NAICS and NAPCS. The ECPC follows a robust review process, inclusive of public comment, trilateral negotiations among the U.S., Canada and Mexico, and expert engagement across Federal agency staff.

The results of the ECPC's robust process are recommendations for proposed revisions to NAICS and NAPCS to CSOTUS. CSOTUS holds the responsibility of reviewing the recommendations and issuing final decisions for any revisions to the NAICS and NAPCS, per statutory authority in the PRA.

IV. Interagency Technical Working Group: The Office of the Chief Statistician of the United States (CSOTUS) convened an Interagency Technical Working Group on the Bioeconomy (Working Group) to provide recommendations on bioeconomy-related revisions for NAICS and NAPCS to the ECPC. Agency participation was solicited from the Interagency Council on Statistical Policy (ICSP). The ICSP comprises 13 Principal Statistical Agencies¹¹, and 24 Chief Financial Officer (CFO) agencies¹² as well as agencies that are NAICS data users/stakeholders. The Working Group members were nominated by their agency Statistical Official. The Working Group is comprised of career staff from Federal agencies representing OMB, Department of Agriculture, Department of Energy, Small Business Administration, Bureau of Census, Bureau of Economic Analysis, Environmental Protection Agency, National Science Foundation, Bureau of Labor Statistics, and the Department of Defense.

The Working Group is charged with developing bioeconomy-related recommendations for revisions to NAICS and NAPCS that would promote accurate and

reliable measurement of the bioeconomy, and maintain the integrity of federal statistical products. Upon completion, these recommendations will be provided to OMB and the ECPC. The ECPC will consider these recommendations in the development of proposed revisions for the 2027 NAICS and NAPCS.

V. Considerations for the Working Group: The Working Group, through OMB, is seeking input on how to best identify, classify, and measure bioeconomy manufacturing, technology, and products, including those that are primarily or exclusively: a) biobased, b) components of traditional manufacturing processes, and c) nascent biobased processes and products. Importantly, input should include information on how particular industries or products are linked to the bioeconomy, and where appropriate and available, evidence to support your input should be provided. This will afford the Working Group the opportunity to use existing evidence to inform its recommendations.

To restate, the bioeconomy refers to a segment of the total economy utilizing and/or derived from biological resources, and includes manufacturing processes, technologies, products, and services. These may encompass, wholly or in part, industries and products including fuel, food, medicine, chemicals, and technology.¹³

Examples within these domains include: Energy (fuel, biomass), Agriculture (food, genetically modified plants), Health (medicine, genetic products), Manufacturing (biomaterials/chemicals, biobased industrial equipment), Technology (bio-related software, products) and Services (bio-based research and development, production, bio-based waste management, biobased resource management).

The Working Group will use these comments to inform their recommendations to OMB and ECPC as describes earlier.

V. Questions:

1. What information and what high priority concerns should the Working Group consider in making these recommendations for potential revisions to the NAICS

and NAPCS that would enable characterization of the economic value of the U.S. bioeconomy?

2. Which quantitative economic indicators and processes are currently used to measure the contributions of the U.S. bioeconomy? Are these indicators reasonably accurate measures of the product components, scope, and value, of the bioeconomy; and, please explain why?
3. Which industries not currently measured as a unique classification in NAICS related to the bioeconomy should be considered? Similarly, which products not currently measured as a unique classification in NAPCS related to the bioeconomy should be considered? Please describe how a unique classification for such industry or product would meet the principles of NAICS and NAPCS. Please also include a description of the industry or product, with specific examples. Please also provide an explanation of how such industry or product would advance understanding of measuring the bioeconomy.
4. How might potential changes to the NAICS impact existing industry measurements, such as assessing changes in the economic output across current industries, time series measures, or data accuracy?
5. What role can the NAPCS fill in order to advance measurement of biomanufacturing and biotechnology?
6. Biobased processes and products that are embedded in traditional industries pose challenges for differentiation and measurement. Are there methodologies that can differentiate these bioeconomy processes from current manufacturing processes to enable measurement? If yes, please explain.
7. What potential bioeconomy measurement strategies might be considered other than revisions to and inclusion in the NAICS or NAPCS? For example, are there

ways the Federal Government could better collect information to provide better measurement on biobased processes or products in current industries?

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Chief, Statistical and Science Policy Branch,
Office of Information and Regulatory Affairs,

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¹ Executive Order 14081 of September 12, 2022 (Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy) - *See* <https://www.federalregister.gov/documents/2022/09/15/2022-20167/advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american>.

² North American Industrial Classification System – *See* <http://www.census.gov/naics>

³ North American Product Classification System - *See* <https://www.census.gov/naics/napcs>

⁴ Paperwork Reduction Act 1995 44I.S.C. 3504(e)(1) - *See* USCODE-2021-title44-chap35-subchapI-sec3504.pdf (govinfo.gov)

⁵ Paperwork Reduction Act 1995 44I.S.C. 3504(e)(3) - *See* USCODE-2021-title44-chap35-subchapI-sec3504.pdf (govinfo.gov).

⁶ Statistical Policy Directive #8 - *See* 2021-27536.pdf (govinfo.gov) .

⁷ NAICS *See* - Federal Register: North American Industry Classification System (NAICS) Updates for 2022; Update of Statistical Policy Directive No. 8, Standard Industrial Classification of Establishments; and Elimination of Statistical Policy Directive No. 9, Standard Industrial Classification of Enterprises

⁸ NAICS *See* - Federal Register: North American Industry Classification System (NAICS) Updates for 2022; Update of Statistical Policy Directive No. 8, Standard Industrial Classification of Establishments; and Elimination of Statistical Policy Directive No. 9, Standard Industrial Classification of Enterprises

⁹ Revision for 2022; Update of Statistical Policy Directive No. 8, North American Industry Classification System - *See* <https://www.govinfo.gov/content/pkg/FR-2021-12-21/pdf/2021-27536.pdf>.

¹⁰ North American Product Classification System - *See* <https://www.census.gov/naics/napcs>

¹¹ Paperwork Reduction Act 1995 44I.S.C. 3504(e)(3) *See* 44 USC 3504 - Authority and functions of Director (govregs.com)

¹² *See* 31 USC 901: Establishment of agency Chief Financial Officers (house.gov).

¹³ Executive Order 14081 of September 12, 2022 (Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy) -*See* <https://www.federalregister.gov/documents/2022/09/15/2022-20167/advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american>.